UNIVERSITY OF REGINA

Research Participant Information and Consent Form March 20, 2019

Title of the study: Effects of creatine and caffeine co-supplementation on body composition and muscle performance in trained adults

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Introduction:
You are being invited to participate in this research study because we are interested in determining the effects of creatine and caffeine co-supplementation on body composition, muscle thickness, strength and endurance.

Before you decide to participate, it is important that you understand what the research involves. This consent form will tell you about the study, why the research is being performed, what will happen to you during the study, and the possible benefits, risks, and discomforts.

If you wish to participate, you will be asked to sign this form. Your participation is completely voluntary, so it is up to you to decide whether or not to participate in this study. If you decide to take part in this study, you are free to withdraw at any time without giving any reasons for your decision and your choice not to participate will not affect your relationship with any of the researchers or institutions conducting the research. Please take time to read the following information carefully and feel free to discuss it with your family, friends, and doctor or health professional before you decide.

Why is this study being done?
The purpose of the study is to compare the effects of creatine and caffeine co-supplementation on body composition, muscle thickness, strength and endurance during 6 weeks of resistance training. Creatine is a nitrogen-containing compound naturally produced in the body and found in red meat and seafood, and when given in higher amounts than usually consumed in the diet, may increase muscle mass and muscle strength. Caffeine is a compound found in nuts, seeds, beverages and plant products and has been shown to increase muscle strength and endurance.

Who can participate in this study?
You can participate if you are male or **female** (18-39 years of age) and have been resistance training for ≥ 6 months. In addition, you can not have taken medications that affect muscle biology or creatine monohydrate ≤ 12 weeks prior to the start of resistance training and supplementation; if you have diseases that are known to affect muscle biology (i.e. Crohn's Disease), if you have pre-existing kidney or liver abnormalities, if you plan to travel ≥ 1 week during the study where they have no access to a fitness facility, or if you are vegetarian.

What does the study involve?
If you agree to participate in this study, the following will occur:

You will be given a physical activity questionnaire at the start of the study. This will gather information about leisure, household and work- related physical activity over the past 7 days. The frequency (number of days a week) and duration (daily hours) of specific activities performed will be recorded.

Prior to the start of the study, you will be randomized into one of four groups: Creatine + Caffeine (0.1 g/kg of creatine monohydrate powder + 3 mg/kg of caffeine power]); Creatine (0.1 g/kg of creatine monohydrate powder + 3 mg/kg of caffeine placebo]), Caffeine (3 mg/kg of caffeine + 0.1 g/kg of creatine monohydrate placebo]) or placebo (PLA; 0.1g/kg creatine monohydrate placebo + 3 mg/kg of caffeine placebo). You will mix your supplement powder in water and consume this 60 minutes prior to each resistance training session (5 days/week). Neither you nor the researchers will know which group you are in until the end of the study, but we can find out what group you are in if there is an emergency (i.e. an adverse reaction to the creatine or placebo).

All groups will participate in 6 weeks of resistance training. Resistance training will start on the first day of supplementation. Day 1 will involve chest and biceps exercises, Day 2 will involve leg and core exercises, Day 4 will involve back and triceps exercise and Day 5 will involve shoulders and core exercise. Days 3 and 6 will serve as rest days. This cycle will repeat for 6 weeks.

Although 100% compliance to the resistance training program is the expectation, it is unlikely that all participants will meet this goal. Our hope is that you will be able to complete approximately 90% of the sessions (i.e. 27/30 sessions).

<u>Study measurements:</u>

The following measurements will be performed prior to the intervention (i.e. baseline) and after 6 weeks of supplementation and resistance training:

- Body composition (fat-free mass, fat mass) will be assessing using air-displacement plethymography. This procedure takes 10 minutes.

- Your muscle thickness will be determined using an ultrasound machine on the right side of your body for the elbow flexors (biceps), elbow extensors (triceps), knee flexors (hamstrings), and knee extensors (quadriceps). This procedure will take approximately 30 minutes.

- Your muscular strength will be determined for the **leg press** and chest press. This procedure will take approximately 30 minutes.

- Your muscular endurance will be determined for **leg press** and chest press. This procedure will take approximately 20 minutes.

What are the benefits of participating in this study?
You might improve your body composition, muscle size, strength, and endurance. These benefits are not guaranteed.

What are the possible risks and discomforts?
The resistance training and strength and endurance testing may result in minor muscle pulls and strains. You will be instructed to perform a proper warm-up prior to exercising and this will minimize the risk.

Creatine supplementation has been shown on a few occasions to decrease kidney and liver function in individuals with pre-existing kidney or liver disease. If you have any kidney or liver abnormalities, you should not participate in this study.

Although the dosage of caffeine administered in this study is low and has no related adverse effects, you will be required to refrain for additional caffeine sources > 3 hours prior to consuming the supplement.

What are alternatives to the study?
You do not have to participate in this study to have your body composition, strength or endurance assessed. You could have your body composition determined through an appointment with the Dr. Paul Schwann Center, Faculty of Kinesiology and Health Studies at the University of Regina and this can be performed by a number of different techniques (i.e. skin folds, bio-electrical impedance analysis). You can perform alternative exercises (i.e. free-body exercises such as push-ups and wall squats instead of the resistance exercises in this study) to increase your muscle size, strength and endurance. You could also increase your creatine consumption from your diet by consuming more red meat and seafood products instead of receiving creatine supplementation in this study. You can increase your caffeine consumption by consuming more caffeinated beverages (i.e. coffee, tea) instead of receiving caffeine supplementation in this study.

What happens if I decide to withdraw?
Your participation in this research is voluntary. You may withdraw from this study at any time. You do not have to provide a reason. Your relationships with the researchers or the university will not be affected. If you choose to enter the study and then decide to withdraw at a later time, all data collected about you during your enrolment will be retained for analysis unless you withdraw **from the study by May 1, 2019.**

What happens if something goes wrong?
In the case of a medical emergency related to the study, you should seek immediate care and, as soon as possible, notify the principal investigator. Inform the medical staff you are participating in a clinical study. Necessary medical treatment will be made available at no cost to you. By signing this document, you do not waive any of your legal rights against the sponsor, investigators or anyone else.

What happens after completion of the study?
We will inform you of the overall study results after we have analyzed all data.

What will the study cost me?
You will not be charged for the creatine, caffeine, placebo, or any research-related procedures. You will not be paid for participating in this study. Reimbursement for study-related expenses (e.g. travel, parking, meals) is not available.

Will my participation be kept confidential?
In Saskatchewan, the Health Information Protection Act (HIPA) defines how the privacy of your personal health information must be maintained so that your privacy will be respected. Your name will not be attached to any information, nor mentioned in any study report, nor be made available to anyone except the research team. It is the intention of the research team to publish results of this research in scientific journals and to present the findings at related conferences and workshops, but your identity will not be revealed.

Who do I contact if I have questions about the study?
If you have questions concerning the study you can contact Dr. Darren Candow at 306-585-4906 or 306-209-0280 (24 hour cell).

If you have any questions about your rights as a research subject or concerns about this study, you may contact the Chair of the University of Regina Research Ethics Board at (306) 585-4775 or email research.ethics@uregina.ca. Out of town participants may call collect

Consent statement

- I have read (or someone has read to me) the information in this consent form.
- I understand the purpose and procedures and the possible risks and benefits of the study.
- I have been informed of the alternatives to the study.
- I was given sufficient time to think about it.
- I had the opportunity to ask questions and have received satisfactory answers.

- I am free to withdraw from this study at any time for any reason and the decision to stop taking part will not affect my future relationships at the university.
- I agree to follow the principal investigator's instructions and will tell the principal investigator at once if I feel I have had any unexpected or unusual symptoms.
- I have been informed there is no guarantee that this study will provide any benefits to me.
- I give permission for the use and disclosure of my de-identified personal health information collected for the research purposes described in this form.
- I understand that by signing this document I do not waive any of my legal rights.
- I will be given a signed and dated copy of this consent form.
- I give permission for my family physician to be informed about my participation in this study if need be:
  - ❑ Yes
  - ❑ No
  - ❑ I do not have a family physician

❑ I agree to participate in this study:

Printed name of participant: _____

Signature _____ Date_____

Printed name of person obtaining consent: _____

Signature _____ Date_____